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MARGER JOHNSON MCCOLLOM STOLOWITZ  
1030 SW MORRISON ST  
PORTLAND OR 97205

EXAMINER

PREBILIC, P

ART UNIT 3308 PAPER NUMBER 3

DATE MAILED: 09/29/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on Feb. 2, 1997.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- Claim(s) 1 - 75 is/are pending in the application.  
Of the above, claim(s) 25-35, 56-73, and 75 is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) 1-24, 36-55, and 74 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claim(s) 1-75 are subject to restriction or election requirement.

#### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been
- received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- Notice of Reference Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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### **DETAILED ACTION**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-24, 36-55, and 74, drawn to the method of producing a biomaterial, classified in class 600, subclass 36.
- II. Claims 25-35, 56-73, and 75, drawn to a prosthetic device and its method of use, classified in class 623, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made or used. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product made or used could have been made by a materially different process such as the energy absorbing material could be applied to the tissue instead of the tropoelastin or the stent could be coated with polymerized tropoelastin.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Jerry Marger on September 22, 1997 a provisional election was made **with traverse** to prosecute the invention of Group I, claims 1-24, 36-55, and 74. **Affirmation of this election must be made by applicant in responding to this Office**

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**action.** Claims 25-35, 56-73, and 75 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Claims 17, 50, 51, 52, and 54 recite the limitation "stromal support matrix", "stromal support matrix", "tropoelastin layer", "cells", and "inner lining", respectively. There is insufficient antecedent basis for these limitations in the claim.

Claims 15, 17, 21-24, 41, 45, 47, 48, 49, and 53-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In re claims 15, 21, 48, and 54, it is unclear how the intended use language of these claims is intended to further limit or modify the method of the base claim since the claims are drawn to a method of making.

In re claim 17, it appears that "comprise" should be plural to be proper grammatically.

In re claims 22 and 55, the structure recited in the thereby clause is not provided for by the structure recited in the body of the claim, and thus, the thereby clause is improper.

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In re claims 23, line 1, claim 49, line 2 and claim 53, line 2, “an” should be --a-- to be proper grammatically.

In re claim 23, the preamble is inconsistent with the claim body because the preamble sets forth a ‘method of using a tropoelastin biomaterial’, yet the claim body sets forth a ‘method of making a tropoelastin biomaterial fused onto a tissue substrate’.

In re claim 24, line 6, the “and” appears improper at this point in the claim; on line 28, “substratel” is misspelled.

In re claim 41, on line 3, “support” should be ---support member--- in order to be consistent with the previously used terminology; on line 4, “sheet” should be ---sheet or tube--- in order to be consistent with the previously used terminology.

In re claim 45, the dependency of the claim is improper since claim 367 does not exist.

In re claim 47, line 6-8, it is unclear what the device is formed into because “for use in biomedical applications” does not positively require any particular structure or device, only a use.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-24, 36-55, and 74 are rejected under 35 U.S.C. 102(a) as anticipated by Gregory et al (WO 96/14807) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gregory et al (WO 96/14807) in view of Labroo et al (US 5,428,014).

Gregory et al is viewed as anticipating the present claims because the soluble elastin used therein is tropoelastin even though it is not called such in the disclosure because the elastin is uncrosslinked and unpolymerized elastin (i.e. this is definition of tropoelastin in the present specification); see the entire disclosure of Gregory et al.

Alternatively, one may not consider the claims anticipated by Gregory et al because tropoelastin is not explicitly stated therein. However, the Examiner posits that it would have been obvious to use tropoelastin as the elastin-like material of Gregory et al because it is so similar to elastin in tissue binding properties that it is considered interchangeable therewith; see Labroo et al on Col. 9, lines 1-26. Furthermore, it is prima fascia obvious to use tropoelastin in the Gregory et al invention because it is an elastin-based material as required by Gregory et al.

Claims 47, 48, and 53-55 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Labroo et al (US 5,428,014); see the whole document, especially Col. 1, line 63 to Col. 2, line 43; Col. 9, lines 1-13.

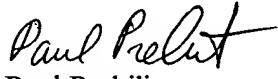
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Claims 36-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Labroo et al (US 5,428,014). Labroo et al teaches using tropoelastin to make a medical devices as claimed, but fails to disclose the use therewith as a coating material or other forms as claimed. However, the Examiner posits that it would have been clearly obvious to utilize the Labroo et al material in various other forms such as coatings since whole biomedical devices are made therefrom.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss, can be reached on (703) 308-2702. The fax phone number for this Group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

  
Paul Prebilic  
Primary Examiner  
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